

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-38 (Cancelled).

39. (New) A dry powder inhaler pharmaceutical composition comprising a mixture of one or more particulate active ingredients and a particulate roller-dried anhydrous β -lactose excipient said excipient having a particle size comprised between 50 and 250 μ m.

40. (New) The composition of Claim 39, in which the particulate roller-dried anhydrous β -lactose excipient has a particle size comprised between 100 and 160 μ m.

41. (New) The composition of Claim 39, in which the particulate roller-dried anhydrous β -lactose excipient has a rugosity comprised between 1.9 and 2.4.

42. (New) The composition of Claim 39, in which the particulate roller-dried anhydrous β -lactose excipient has a particle size comprised between 50 and 250 μ m, and a rugosity comprised between 1.9 and 2.4.

43. (New) The composition of Claim 39, in which the particulate roller-dried anhydrous β -lactose excipient has a particle size comprised between 100 and 160 μ m, and a rugosity comprised between 1.9 and 2.4.

Please, do
not enter
AB
5/31/05
Examiner.

44. (New) The composition of Claim 39, in which the particulate roller-dried anhydrous β -lactose excipient is prepared from a lactose solution in demineralized water fed between two counter-rotating drums, which are steam-heated, and after drying scraped from the surface of the drums by knives.

45. (New) The composition of Claim 39, in which the particulate pharmaceutically active ingredients are a particulate solid with a particle diameter between 0.5 and 6 μ m.

46. (New) The composition of Claim 39, in which the weight ratio of the pharmaceutically active ingredients in relation to the excipient is from 0.1/100 to 50/100.

47. (New) The composition of Claim 39, in which the particulate pharmaceutically active ingredients are selected from the group consisting of mucolytics, steroids, sympathomimetics, proteins, peptides, inhibitors of mediators release and mixtures thereof.

48. (New) The composition of Claim 47, in which the composition comprises a mucolytic agent, which is L-lysine N-acetylcysteinate, as the pharmaceutically active ingredient.

49. (New) The composition of Claim 39, which comprises a mixture of particulate L-lysine N-acetylcysteinate and roller-dried anhydrous β -lactose excipient, said excipient being constituted by particles of 100 to 160 μ m in size and of 1.9 to 2.4 in rugosity.

50. (New) The composition of Claim 49, in which the weight ratio of particulate L-lysine N-acetylcysteinate in relation to the particulate roller-dried anhydrous β -lactose excipient is between $\frac{1}{2}$ and $\frac{1}{4}$.

51. (New) The composition of Claim 39, wherein said pharmaceutically active ingredient is budesonide.

52. (New) The composition of Claim 39, wherein said pharmaceutically-active ingredient is salbutamol.

53. (New) The composition of Claim 39, wherein said pharmaceutically-active ingredient is sodium cromoglycate.

54. (New) A process for the preparation of a dry powder inhaler pharmaceutical composition comprising a mixture of a particulate pharmaceutically-active ingredient and a particulate roller-dried anhydrous β -lactose lactose excipient, which comprises a step of mixing a dry particulate pharmaceutical active ingredient with a particulate roller-dried anhydrous β -lactose excipient.